

CMS Library
C2-07-13
7500 Security Blvd.
Baltimore, Maryland 21244

II

106TH CONGRESS
1ST SESSION

S. 578

To ensure confidentiality with respect to medical records and health care-related information, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 10, 1999

Mr. JEFFORDS (for himself and Mr. DODD) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To ensure confidentiality with respect to medical records and health care-related information, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Health Care Personal Information Nondisclosure Act of
6 1999” or the “Health Care PIN Act”.

7 (b) TABLE OF CONTENTS.—The table of contents for
8 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purposes.
- Sec. 4. Definitions.

TITLE I—INDIVIDUAL'S RIGHTS

Subtitle A—Review of Protected Health Information by Subjects of the Information

- Sec. 101. Inspection and copying of protected health information.
- Sec. 102. Amendment of protected health information.
- Sec. 103. Notice of confidentiality practices.

Subtitle B—Establishment of Safeguards

- Sec. 111. Establishment of safeguards.
- Sec. 112. Accounting for disclosures.

TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

- Sec. 201. General rules regarding use and disclosure.
- Sec. 202. Procurement of authorizations for disclosure of protected health information for treatment, payment, and health care operations.
- Sec. 203. Authorizations for disclosure of protected health information other than for treatment, payment, or health care operations.
- Sec. 204. Next of kin and directory information.
- Sec. 205. Emergency circumstances.
- Sec. 206. Oversight.
- Sec. 207. Public health.
- Sec. 208. Health research.
- Sec. 209. Disclosure in civil, judicial, and administrative procedures.
- Sec. 210. Disclosure for law enforcement purposes.
- Sec. 211. Disclosures for postmarketing adverse experience reporting for human drug and licensed biological products.
- Sec. 212. Payment card and electronic payment transaction.
- Sec. 213. Standards for electronic disclosures.
- Sec. 214. Individual representatives.
- Sec. 215. Limited liability for law enforcement officers.
- Sec. 216. No liability for permissible disclosures.

TITLE III—SANCTIONS

Subtitle A—Criminal Provisions

- Sec. 301. Wrongful disclosure of protected health information.
- Sec. 302. Debarment for crimes.

Subtitle B—Civil Sanctions

- Sec. 311. Civil penalty.
- Sec. 312. Procedures for imposition of penalties.
- Sec. 313. Report on use of existing enforcement mechanisms.
- Sec. 314. Civil action by individuals.

TITLE IV—MISCELLANEOUS

- Sec. 401. Relationship to other laws.
- Sec. 402. Effective date.

1 SEC. 2. FINDINGS.

2 The Congress finds that—

1 (1) individuals have a right of confidentiality
2 with respect to their personal health information and
3 records;

4 (2) with respect to information about medical
5 care and health status, the traditional right of con-
6 fidentiality is at risk;

7 (3) an erosion of the right of confidentiality
8 may reduce the willingness of patients to confide in
9 physicians and other practitioners, thus jeopardizing
10 quality health care;

11 (4) an individual's confidentiality right means
12 that an individual's consent is needed to disclose his
13 or her protected health information, except in rare
14 and limited circumstances required by the public in-
15 terest;

16 (5) any disclosure of protected health informa-
17 tion should be limited to that information or portion
18 of the medical record necessary to fulfill the purpose
19 of the disclosure;

20 (6) incentives need to be created to use non-
21 identifiable health information where appropriate;

22 (7) the availability of timely and accurate per-
23 sonal health data for the delivery of health care serv-
24 ices throughout the Nation is needed;

1 (8) personal health care data may be essential
2 for selected types of medical research;

3 (9) public health uses of personal health data
4 are critical to both personal health as well as public
5 health; and

6 (10) confidentiality of an individual's health in-
7 formation must be assured without jeopardizing the
8 pursuit of clinical and epidemiological research un-
9 dertaken to improve health care and health outcomes
10 and to assure the quality and efficiency of health
11 care.

12 **SEC. 3. PURPOSES.**

13 The purpose of this Act is to—

14 (1) establish strong and effective mechanisms
15 to protect against the unauthorized and inappropri-
16 ate use of protected health information that is cre-
17 ated or maintained as part of health care treatment,
18 diagnosis, enrollment, payment, plan administration,
19 testing, or research processes;

20 (2) promote the efficiency and security of the
21 health information infrastructure so that members
22 of the health care community may more effectively
23 exchange and transfer health information in a man-
24 ner that will ensure the confidentiality of protected

1 health information without impeding the delivery of
2 high quality health care;

3 (3) create incentives to turn personal health in-
4 formation into nonidentifiable health information for
5 oversight, health research, public health, law en-
6 forcement, judicial, and administrative purposes,
7 where appropriate; and

8 (4) establish strong and effective remedies for
9 violations of this Act.

10 **SEC. 4. DEFINITIONS.**

11 As used in this Act:

12 (1) ACCREDITING BODY.—The term “accredit-
13 ing body” means a national body, committee, organi-
14 zation, or institution (such as the Joint Commission
15 on Accreditation of Health Care Organizations or
16 the National Committee for Quality Assurance) that
17 has been authorized by law or is recognized by a
18 health care regulating authority as an accrediting
19 entity or any other entity that has been similarly au-
20 thorized or recognized by law to perform specific ac-
21 creditation, licensing or credentialing activities.

22 (2) AGENT.—The term “agent” means a person
23 who represents and acts for another under the con-
24 tract or relation of agency, or whose function is to
25 bring about, modify, affect, accept performance of,

1 or terminate contractual obligations between the
2 principal and a third person, including a contractor.

3 (3) ANONYMOUS LINK.—

4 (A) IN GENERAL.—The term “anonymous
5 link” means a number assigned to nonidentifi-
6 able health information which, by itself, con-
7 tains no information about an individual, but
8 which, under specific, controlled conditions, can
9 be used to link to additional health information
10 about the same individual which may be used to
11 identify that individual.

12 (B) DISCLOSURE.—Any subsequent disclo-
13 sure of an anonymous link with any information
14 which, together with information previously dis-
15 closed with the same link might reasonably be
16 used to identify an individual, shall be consid-
17 ered to be a disclosure of protected health infor-
18 mation. Such a disclosure shall convert any pre-
19 viously disclosed, nonidentifiable information
20 with the same link into protected health infor-
21 mation.

22 (4) COMMON RULE.—The term “common rule”
23 means the Federal policy for the protection of
24 human subjects from research risks originally pub-
25 lished as 56 Federal Register 28.012 (et seq.) (June

1 18, 1991) as adopted and implemented by a Federal
2 department or agency.

3 (5) DISCLOSE.—The term “disclose” means to
4 release, transfer, provide access to, or otherwise di-
5 vulge protected health information to any person
6 other than the individual who is the subject of such
7 information. Such term includes the initial disclosure
8 and any subsequent disclosures of protected health
9 information.

10 (6) EMPLOYER.—The term “employer” has the
11 meaning given such term under section 3(5) of the
12 Employee Retirement Income Security Act of 1974
13 (29 U.S.C. 1002(5)), except that such term shall in-
14 clude only employers of two or more employees.

15 (7) HEALTH CARE.—The term “health care”
16 means—

17 (A) preventive, diagnostic, therapeutic, re-
18 habilitative, maintenance, or palliative care, in-
19 cluding appropriate assistance with disease or
20 symptom management and maintenance, coun-
21 seling, service, or procedure—

22 (i) with respect to the physical or
23 mental condition of an individual; or

24 (ii) affecting the structure or function
25 of the human body or any part of the

1 human body, including the banking of
2 blood, sperm, organs, or any other tissue;
3 or

4 (B) pursuant to a prescription or medical
5 order any sale or dispensing of a drug, device,
6 equipment, or other health care related item to
7 an individual, or for the use of an individual.

8 (8) HEALTH CARE OPERATIONS.—The term
9 “health care operations” means services provided by
10 or on behalf of a health plan or health care provider
11 for the purpose of carrying out the management
12 functions of a health care provider or health plan, or
13 implementing the terms of a contract for health plan
14 benefits. Such term means—

15 (A) conducting quality assurance activities
16 or outcomes assessments;

17 (B) reviewing the competence or qualifica-
18 tions of health care professionals;

19 (C) performing accreditation, licensing, or
20 credentialing activities;

21 (D) analysis of health plan claims or
22 health care records data;

23 (E) evaluating health plan and provider
24 performance;

1 (F) carrying out utilization review,
2 precertification or preauthorization of services;

3 (G) underwriting or experience rating of
4 health plans;

5 (H) conducting or arranging for auditing
6 services; or

7 (I) such other services as the Secretary de-
8 termines appropriate.

9 (9) HEALTH CARE PROVIDER.—The term
10 “health care provider” means a person, who with re-
11 spect to a specific item of protected health informa-
12 tion, receives, creates, uses, maintains, or discloses
13 the information while acting in whole or in part in
14 the capacity of—

15 (A) a person who is licensed, certified, reg-
16 istered, or otherwise authorized by Federal or
17 State law to provide an item or service that
18 constitutes health care in the ordinary course of
19 business, or practice of a profession;

20 (B) a Federal, State, or employer spon-
21 sored program that directly provides items or
22 services that constitute health care to bene-
23 ficiaries; or

1 (C) an officer, employee, or agent of a per-
2 son described in subparagraph (A) or (B) that
3 is engaged in the provision of health care.

4 (10) HEALTH OR LIFE INSURER.—The term
5 “health or life insurer” means a health insurance
6 issuer as defined in section 9805(b)(2) of the Inter-
7 nal Revenue Code of 1986 or a life insurance com-
8 pany as defined in section 816 of such Code.

9 (11) HEALTH OVERSIGHT AGENCY.—The term
10 “health oversight agency” means a person who, with
11 respect to a specific item of protected health infor-
12 mation, receives, creates, uses, maintains, or dis-
13 closes the information while acting in whole or in
14 part in the capacity of—

15 (A) a person who performs or oversees the
16 performance of an assessment, evaluation, de-
17 termination, or investigation, relating to the li-
18 censing, accreditation, or credentialing of health
19 care providers; or

20 (B) a person who—

21 (i) performs or oversees the perform-
22 ance of an audit, assessment, evaluation,
23 determination, or investigation relating to
24 the effectiveness of, compliance with, or
25 applicability of, legal, fiscal, medical, or

1 scientific standards or aspects of perform-
2 ance related to the delivery of, or payment
3 for, health care; and

4 (ii) is a public agency, acting on be-
5 half of a public agency, acting pursuant to
6 a requirement of a public agency, or carry-
7 ing out activities under a Federal or State
8 law governing the assessment, evaluation,
9 determination, investigation, or prosecution
10 described in subparagraph (A).

11 (12) HEALTH PLAN.—The term “health plan”
12 means any health insurance plan, including any hos-
13 pital or medical service plan, dental or other health
14 service plan or health maintenance organization
15 plan, provider sponsored organization, or other pro-
16 gram providing or arranging for the provision of
17 health benefits. Such term includes employee welfare
18 benefits plans and group health plans as defined in
19 sections 3 and 607 of the Employee Retirement In-
20 come Security Act of 1974 (29 U.S.C. 1002 and
21 1167).

22 (13) HEALTH RESEARCHER.—The term “health
23 researcher” means a person, or an officer, employee
24 or independent contractor of a person, who receives
25 protected health information as part of a systematic

1 investigation, testing or evaluation designed to de-
2 velop or contribute to generalized scientific and clini-
3 cal knowledge.

4 (14) INDIVIDUAL REPRESENTATIVE.—The term
5 “individual representative” means a person who is
6 authorized by law (based on grounds other than the
7 individual being a minor), or by an instrument rec-
8 ognized under law, to act as an agent, attorney,
9 proxy, or other legal representative of a protected in-
10 dividual. Such term includes a health care power of
11 attorney.

12 (15) INSTITUTIONAL REVIEW BOARD.—The
13 term “institutional review board” means a review
14 panel, that is generally associated with a particular
15 university or other research institution, that is re-
16 sponsible for implementing Federal human subject
17 protection requirements for research conducted at or
18 supported by the university or institution involved.

19 (16) LAW ENFORCEMENT INQUIRY.—The term
20 “law enforcement inquiry” means a lawful investiga-
21 tion conducted by an appropriate government agency
22 or official inquiring into a violation of, or failure to
23 comply with, any criminal or civil statute or any reg-
24 ulation, rule, or order issued pursuant to such a
25 statute.

1 (17) NETWORK PLAN.—The term “network
2 plan” means health care coverage provided under a
3 health plan under which the financing and delivery
4 of health care are provided, in whole or in part,
5 through a defined set of health care providers under
6 contract with the health plan.

7 (18) NONIDENTIFIABLE HEALTH INFORMA-
8 TION.—The term “nonidentifiable health informa-
9 tion” means any information that would otherwise
10 be protected health information except that such in-
11 formation does not directly reveal the identity of the
12 individual whose health or health care is the subject
13 of the information and there is no reasonable basis
14 to believe that such information could be used, either
15 alone or with other information that is, or should
16 reasonably be known to be, available to predictable
17 recipients of such information, to reveal the identity
18 of that individual.

19 (19) ORIGINATING PROVIDER.—The term “orig-
20 inating provider” means a health care provider who
21 creates or originates medical information that is or
22 that becomes protected health information.

23 (20) PAYMENT.—The term “payment”
24 means—

25 (A) the activities undertaken by—

1 (i) or on behalf of a health plan to de-
2 termine its responsibility for coverage
3 under the plan and the actual payment
4 under such plan; and

5 (ii) a health care provider to obtain
6 payment for items or services provided
7 under a health plan or provided based on
8 a determination by the health plan of re-
9 sponsibility for coverage under the plan;
10 and

11 (B) activities undertaken as described in
12 subparagraph (A) including—

13 (i) billing, claims management, medi-
14 cal data processing or other administrative
15 services;

16 (ii) determinations of coverage or ad-
17 judication of health benefit claims; and

18 (iii) review of health care services with
19 respect to medical necessity, coverage
20 under a health plan, appropriateness of
21 care, or justification of charges.

22 (21) PERSON.—The term “person” means a
23 government, governmental subdivision, agency or au-
24 thority; corporation; company; association; firm;
25 partnership; society; estate; trust; joint venture; indi-

1 vidual; individual representative; tribal government;
2 and any other legal entity.

3 (22) PROTECTED HEALTH INFORMATION.—The
4 term “protected health information” means any in-
5 formation (including demographic information)
6 whether or not recorded in any form or medium—

7 (A) that relates to the past, present or
8 future—

9 (i) physical or mental health or condi-
10 tion of an individual (including the condi-
11 tion or other attributes of individual cells
12 or their components);

13 (ii) provision of health care to an indi-
14 vidual; or

15 (iii) payment for the provision of
16 health care to an individual;

17 (B) that is created or received by a health
18 care provider, health plan, health researcher,
19 health oversight agency, public health authority,
20 employer, law enforcement official, health or life
21 insurer, school or university; and

22 (C) that is not nonidentifiable health infor-
23 mation.

24 (23) PUBLIC HEALTH AUTHORITY.—The term
25 “public health authority” means an authority or in-

1 strumentality of the United States, a tribal govern-
2 ment, a State, or a political subdivision of a State
3 that is—

4 (A) primarily responsible for public health
5 matters; and

6 (B) primarily engaged in activities such as
7 injury reporting, public health surveillance, and
8 public health investigation or intervention.

9 (24) SCHOOL OR UNIVERSITY.—The term
10 “school or university” means an institution or place
11 for instruction or education, including an elementary
12 school, secondary school, or institution of higher
13 learning, a college, or an assemblage of colleges
14 united under one corporate organization or govern-
15 ment.

16 (25) SECRETARY.—The term “Secretary”
17 means the Secretary of Health and Human Services.

18 (26) STATE.—The term “State” includes the
19 District of Columbia, Puerto Rico, the Virgin Is-
20 lands, Guam, American Samoa, and the Northern
21 Mariana Islands.

22 (27) TREATMENT.—The term “treatment”
23 means the provision of health care by, or the coordi-
24 nation of health care among, health care providers,
25 or the referral of a patient from one provider to an-

1 other, or coordination of health care or other serv-
2 ices among health care providers and third parties
3 authorized by the health plan or the plan member.

4 (28) WRITING.—The term “writing” means
5 writing in either a paper-based or computer-based
6 form, including electronic signatures.

7 **TITLE I—INDIVIDUAL’S RIGHTS**
8 **Subtitle A—Review of Protected**
9 **Health Information by Subjects**
10 **of the Information**

11 **SEC. 101. INSPECTION AND COPYING OF PROTECTED**
12 **HEALTH INFORMATION.**

13 (a) IN GENERAL.—At the request of an individual
14 and except as provided in subsection (b), a health care
15 provider, health plan, employer, health or life insurer,
16 school, or university shall permit an individual who is the
17 subject of protected health information or the individual’s
18 designee, to inspect and copy protected health information
19 concerning the individual, including records created under
20 sections 102 and 112, that such entity maintains. The en-
21 tity may set forth appropriate procedures to be followed
22 for such inspection or copying and may require an individ-
23 ual to pay reasonable costs associated with such inspection
24 or copying.

1 (b) EXCEPTIONS.—Unless ordered by a court of com-
2 petent jurisdiction, an entity described in subsection (a)
3 is not required to permit the inspection or copying of pro-
4 tected health information if any of the following conditions
5 are met:

6 (1) ENDANGERMENT TO LIFE OR SAFETY.—

7 The entity determines that the disclosure of the in-
8 formation could reasonably be expected to endanger
9 the life or physical safety of, or cause substantial
10 mental harm to, the individual who is the subject of
11 the record.

12 (2) CONFIDENTIAL SOURCE.—The information
13 identifies, or could reasonably lead to the identifica-
14 tion of, a person who provided information under a
15 promise of confidentiality concerning the individual
16 who is the subject of the information.

17 (3) INFORMATION COMPILED IN ANTICIPATION
18 OF LITIGATION.—The information is compiled
19 principally—

20 (A) in the reasonable anticipation of a
21 civil, criminal, or administrative action or pro-
22 ceeding; or

23 (B) for use in such action or proceeding.

24 (4) RESEARCH PURPOSES.—The information
25 was collected for a research project monitored by an

1 institutional review board, such project is not com-
2 plete, and the researcher reasonably believes that ac-
3 cess would harm the conduct of the research or in-
4 validate or undermine the validity of the research.

5 (c) DENIAL OF A REQUEST FOR INSPECTION OR
6 COPYING.—If an entity described in subsection (a) denies
7 a request for inspection or copying pursuant to subsection
8 (b), the entity shall inform the individual in writing of—

9 (1) the reasons for the denial of the request for
10 inspection or copying;

11 (2) any procedures for further review of the de-
12 nial; and

13 (3) the individual's right to file with the entity
14 a concise statement setting forth the request for in-
15 spection or copying.

16 (d) STATEMENT REGARDING REQUEST.—If an indi-
17 vidual has filed a statement under subsection (c)(3), the
18 entity in any subsequent disclosure of the portion of the
19 information requested under subsection (a) shall include—

20 (1) a copy of the individual's statement; and

21 (2) a concise statement of the reasons for deny-
22 ing the request for inspection or copying.

23 (e) INSPECTION AND COPYING OF SEGREGABLE POR-
24 TION.—An entity described in subsection (a) shall permit
25 the inspection and copying under subsection (a) of any

1 reasonably segregable portion of a record after deletion of
2 any portion that is exempt under subsection (b).

3 (f) DEADLINE.—

4 (1) IN GENERAL.—Except as provided in para-
5 graph (2), an entity described in subsection (a) shall
6 comply with or deny, in accordance with subsection
7 (c), a request for inspection or copying of protected
8 health information under this section not later than
9 30 days after the date on which the entity receives
10 the request.

11 (2) OFF PREMISES.—In the case of a request
12 described in paragraph (1), if the information in-
13 volved is in paper form, located off the premises of
14 the entity involved, and not readily available, the en-
15 tity shall have 60 days to comply with or deny such
16 request.

17 (g) RULES GOVERNING AGENTS.—An agent of an en-
18 tity described in subsection (a) shall not be required to
19 provide for the inspection and copying of protected health
20 information, except where—

21 (1) the protected health information is retained
22 by the agent; and

23 (2) the agent has received in writing a request
24 from the entity involved to fulfill the requirements of
25 this section;

1 at which time such information shall be provided to the
2 requesting entity. Such requesting entity shall comply with
3 subsection (f) with respect to any such information.

4 (h) RULE OF CONSTRUCTION.—This section shall not
5 be construed to require an entity described in subsection
6 (a) to conduct a formal, informal, or other hearing or pro-
7 ceeding concerning a request for inspection or copying of
8 protected health information.

9 **SEC. 102. AMENDMENT OF PROTECTED HEALTH INFORMA-**
10 **TION.**

11 (a) REQUIREMENTS.—

12 (1) IN GENERAL.—Except as provided in sub-
13 sections (b) and (e), not later than 45 days after the
14 date on which a health care provider, health plan,
15 employer, health or life insurer, school, or university
16 receives from an individual a request in writing to
17 amend information that meets the requirements of
18 paragraph (2), such entity shall—

19 (A) make the amendment requested;

20 (B) inform the individual of the amend-
21 ment that has been made; and

22 (C) make reasonable efforts to inform any
23 person to whom the unamended portion of the
24 information was previously disclosed, of any
25 nontechnical amendment that has been made.

1 (2) INFORMATION.—The requirements of this
2 paragraph are that—

3 (A) the information that is the subject of
4 the request is in fact inaccurate; and

5 (B) the entity receiving the request created
6 the information that is at issue.

7 (b) REFUSAL TO AMEND.—If an entity described in
8 subsection (a) refuses to make the amendment requested
9 under such subsection, the entity shall inform the individ-
10 ual in writing of—

11 (1) the reasons for the refusal to make the
12 amendment;

13 (2) any procedures for further review of the re-
14 fusals; and

15 (3) the individual's right to file with the entity
16 a concise statement setting forth the requested
17 amendment and the individual's reasons for dis-
18 agreeing with the refusal.

19 (c) STATEMENT OF DISAGREEMENT.—If an individ-
20 ual has filed a statement of disagreement under subsection
21 (b)(3), the entity involved, in any subsequent disclosure
22 of the disputed portion of the information—

23 (1) shall include a copy of the individual's
24 statement; and

1 (2) may include a concise statement of the rea-
2 sons for not making the requested amendment.

3 (d) RULES GOVERNING AGENTS.—The agent of an
4 entity described in subsection (a) shall not be required to
5 make amendments to protected health information, except
6 where—

7 (1) the protected health information is retained
8 by the agent; and

9 (2) the agent has been asked by such entity to
10 fulfill the requirements of this section.

11 If the agent is required to comply with this section as pro-
12 vided for in paragraph (2), such agent shall be subject
13 to the 45-day deadline described in subsection (a).

14 (e) EXTENSION FOR PAPER RECORDS OFF PREM-
15 ISES.—In the case of a request described in subsection (a),
16 if the information involved is in paper form, located off
17 the premises of the entity involved, and not readily avail-
18 able, the entity shall have 60 days to comply with or deny
19 such request.

20 (f) REPEATED REQUESTS FOR AMENDMENTS.—If an
21 entity described in subsection (a) receives a request for
22 an amendment of information as provided for in such sub-
23 section and a statement of disagreement has been filed
24 pursuant to subsection (c), the entity shall inform the indi-

vidual of such filing and shall not be required to carry out the procedures required under this section.

(g) RULES OF CONSTRUCTION.—This section shall not be construed to—

(1) require that an entity described in subsection (a) conduct a formal, informal, or other hearing or proceeding concerning a request for an amendment to protected health information;

(2) require a provider to amend an individual's record as to the type, duration, or quality of treatment the individual believes he or she should have been provided; or

(3) require any deletion or alteration of the original information.

SEC. 103. NOTICE OF CONFIDENTIALITY PRACTICES.

(a) PREPARATION OF WRITTEN NOTICE.—A health care provider, health plan, health oversight agency, public health authority, employer, health or life insurer, health researcher, school, or university shall post or provide, in writing and in a clear and conspicuous manner, notice of the entity's confidentiality practices, that shall include—

(1) a description of an individual's rights with respect to protected health information;

(2) the uses and disclosures of protected health information authorized under this Act;

1 (3) the procedures for authorizing disclosures of
2 protected health information and for revoking such
3 authorizations;

4 (4) the procedures established by the entity for
5 the exercise of the individual's rights; and

6 (5) the right to obtain a copy of the notice of
7 the confidentiality practices required under this Act.

8 (b) MODEL NOTICE.—The Secretary, after notice
9 and opportunity for public comment, shall develop and dis-
10 seminate model notices of confidentiality practices. Use of
11 the model notice shall serve as an absolute defense against
12 claims of receiving inappropriate notice.

13 **Subtitle B—Establishment of** 14 **Safeguards**

15 **SEC. 111. ESTABLISHMENT OF SAFEGUARDS.**

16 (a) IN GENERAL.—A health care provider, health
17 plan, health oversight agency, public health authority, em-
18 ployer, health or life insurer, health researcher, law en-
19 forcement official, school, or university shall establish and
20 maintain appropriate administrative, technical, and phys-
21 ical safeguards to protect the confidentiality, security, ac-
22 curacy, and integrity of protected health information cre-
23 ated, received, obtained, maintained, used, transmitted, or
24 disposed of by such entity.

1 (b) REGULATIONS.—The Secretary shall have the au-
2 thority to promulgate regulations for the implementation
3 of subsection (a).

4 (c) RULE OF CONSTRUCTION.—Safeguards to protect
5 the security of protected health information under sub-
6 section (a) shall include the implementation of policies or
7 procedures to consider whether protected health informa-
8 tion is essential for a use or disclosure undertaken by an
9 entity described in such subsection.

10 **SEC. 112. ACCOUNTING FOR DISCLOSURES.**

11 (a) IN GENERAL.—

12 (1) HEALTH RELATED ENTITIES.—Except as
13 provided in paragraph (3), a health care provider,
14 health plan, health oversight agency, public health
15 authority, employer, health or life insurer, health re-
16 searcher, law enforcement official, school, or univer-
17 sity shall establish and maintain, with respect to any
18 protected health information disclosure, a record of
19 such disclosure in accordance with regulations issued
20 by the Secretary.

21 (2) AGENT.—Except as provided in paragraph
22 (3), an agent shall maintain a record of its disclo-
23 sures made pursuant to sections 205 through 212.

24 (3) EXCEPTION.—A record of disclosures under
25 this subsection is not required with respect to disclo-

1 sures made to officers or employees of the entity
2 that maintains the record involved who, in the per-
3 formance of their duties, have a need for the pro-
4 tected health information.

5 (b) RECORD OF DISCLOSURE.—A record established
6 under subsection (a) shall be maintained for not less than
7 7 years.

8 **TITLE II—RESTRICTIONS ON** 9 **USE AND DISCLOSURE**

10 **SEC. 201. GENERAL RULES REGARDING USE AND DISCLO-** 11 **SURE.**

12 (a) PROHIBITION.—

13 (1) GENERAL RULE.—A health care provider,
14 health plan, health oversight agency, public health
15 authority, employer, health or life insurer, health re-
16 searcher, law enforcement official, school, or univer-
17 sity may not disclose protected health information
18 except as authorized under this title.

19 (2) RULE OF CONSTRUCTION.—Disclosure of
20 health information in the form of nonidentifiable
21 health information shall not be construed as a dis-
22 closure of protected health information.

23 (b) USE OR DISCLOSURE OF PROTECTED HEALTH
24 INFORMATION WITHIN AN ENTITY.—

1 (1) IN GENERAL.—An entity described in sub-
2 section (a) may use protected health information or
3 disclose such information within the entity if such
4 use or disclosure is made pursuant to an authoriza-
5 tion under section 202 or 203 and consistent with
6 the limitations under subsection (d) on the scope of
7 disclosure.

8 (2) AGENTS.—Disclosure to agents of an entity
9 described in subsection (a) shall be considered as a
10 disclosure within an entity.

11 (c) DISCLOSURE BY AGENTS.—An agent who receives
12 protected health information from an entity described in
13 subsection (a) shall be subject to all rules of disclosure
14 and safeguard requirements under this title.

15 (d) SCOPE OF DISCLOSURE.—Every disclosure of
16 protected health information by an entity under this title
17 shall be limited to the information necessary to accomplish
18 the purpose for which the information is disclosed.

19 (e) NO GENERAL REQUIREMENT TO DISCLOSE.—
20 Nothing in this title permitting the disclosure of protected
21 health information shall be construed to require such dis-
22 closure.

23 (f) IDENTIFICATION OF DISCLOSED INFORMATION AS
24 PROTECTED INFORMATION.—Except as otherwise pro-
25 vided in this title, protected health information may not

1 be disclosed unless such information is clearly identified
2 as protected health information that is subject to this Act.

3 (g) CREATION OF NONIDENTIFIABLE INFORMA-
4 TION.—An entity described in subsection (a) may disclose
5 protected health information to an employee or agent of
6 the entity for purposes of creating nonidentifiable infor-
7 mation, if the entity prohibits the employee or agent of
8 the entity from using or disclosing the protected health
9 information for purposes other than the sole purpose of
10 creating nonidentifiable information as specified by the en-
11 tity.

12 (h) DEEMED DISCLOSURES OF PROTECTED HEALTH
13 INFORMATION.—

14 (1) IN GENERAL.—Any individual or entity who
15 manipulates a nonidentifiable database in order to
16 identify an individual shall be deemed to have dis-
17 closed protected health information.

18 (2) DISCLOSURE OR TRANSMISSION OF AN
19 ANONYMOUS LINK.—The disclosure or transmission
20 of an anonymous link with any information which,
21 together with information previously disclosed with
22 the same link, might reasonably be used to identify
23 an individual, shall be deemed to be a disclosure of
24 protected health information. Such a disclosure shall
25 have the effect of converting any previously dis-

1 closed, nonidentifiable information with the same
2 link into the protected health information.

3 **SEC. 202. PROCUREMENT OF AUTHORIZATIONS FOR DIS-**
4 **CLOSURE OF PROTECTED HEALTH INFORMA-**
5 **TION FOR TREATMENT, PAYMENT, AND**
6 **HEALTH CARE OPERATIONS.**

7 (a) REQUIREMENTS RELATING TO EMPLOYERS,
8 HEALTH PLANS, UNINSURED INDIVIDUALS, AND PROVID-
9 ERS.—

10 (1) IN GENERAL.—To meet the requirements
11 relating to the authorized disclosure of protected
12 health information under section 201, an authoriza-
13 tion form must be secured for each individual in
14 connection with treatment, payment and health care
15 operations.

16 (2) CONSOLIDATED AUTHORIZATION.—A single
17 authorization may be secured for each individual in
18 connection with treatment, payment, and health care
19 operations.

20 (3) EMPLOYERS.—Every employer offering a
21 health plan to its employees shall, at the time of,
22 and as a condition of enrollment in the health plan,
23 obtain a signed, written authorization that is a legal,
24 informed authorization concerning the use and dis-
25 closure of protected health information for treat-

1 ment, payment, and health care operations with re-
2 spect to each individual who is eligible to receive
3 care under the health plan.

4 (4) HEALTH PLANS.—Every health plan offer-
5 ing enrollment to individual or non-employer groups
6 shall, at the time of, and as a condition of enroll-
7 ment in the health plan, obtain a signed, written au-
8 thorization that is a legal, informed authorization
9 concerning the use and disclosure of protected health
10 information for treatment, payment, and health care
11 operations with respect to each individual who is eli-
12 gible to receive care under the plan.

13 (5) UNINSURED.—An originating provider pro-
14 viding health care to an uninsured individual, shall
15 obtain a signed, written authorization that is a legal,
16 informed authorization concerning the use and dis-
17 closure of protected health information, in providing
18 health care or arranging for health care from other
19 providers or seeking payment for the provision of
20 health care services.

21 (6) PROVIDERS.—Every health care provider
22 providing health care to an individual who has not
23 given an authorization under paragraph (3), (4), or
24 (5), shall, at the time of providing such care, obtain
25 a signed, written authorization concerning the use

1 and disclosure of protected health information for
2 treatment, payment, and health care operations with
3 respect to such individual. Nothing in this section
4 shall be construed to require that a health care pro-
5 vider secure an authorization in addition to an au-
6 thorization secured under paragraph (3), (4), or (5).

7 (b) REQUIREMENTS FOR INDIVIDUAL AUTHORIZA-
8 TION.—To be valid, an authorization to disclose protected
9 health information shall—

10 (1) identify the individual involved;

11 (2) describe the nature of the health care infor-
12 mation to be disclosed;

13 (3) identify the type of person to whom the in-
14 formation is to be disclosed;

15 (4) describe the purpose of the disclosure, in-
16 cluding whether the information may be used for
17 disease management or medication compliance;

18 (5) be subject to revocation by the individual
19 and indicate that the authorization is valid until rev-
20 ocation by the individual; and

21 (6)(A) be either—

22 (i) in writing, dated, and signed by the in-
23 dividual; or

(ii) in electronic form, dated and authenticated by the individual using a unique identifier; and

(B) not have been revoked under paragraph (c).

(c) REVOCATION OF AUTHORIZATION.—

(1) IN GENERAL.—An individual may revoke in writing an authorization under this section at any time, unless the disclosure that is the subject of the authorization is required to effectuate payment for health care that has been provided to the individual for which the individual has not agreed to assume personal financial responsibility.

(2) EXCEPTION FOR SELF-PAYMENT.—An individual may revoke a prior authorization for payment or health care operations described in paragraphs (1) through (6) of subsection (a) prior to a single or series of encounters with a health care provider if such individual has agreed to assume personal financial responsibility for the treatment.

(3) HEALTH PLANS.—With respect to a health plan, the authorization of an individual is deemed to be revoked at the time of the cancellation or non-renewal of enrollment in the health plan, except as may be necessary to complete health care operations

1 and payment requirements related to the individual's
2 period of enrollment.

3 (4) ACTIONS.—An individual may not maintain
4 an action against a person for disclosure of pro-
5 tected health information made in good faith reli-
6 ance on the individual's authorization at the time
7 disclosure was made.

8 (d) RECORD OF INDIVIDUAL'S AUTHORIZATIONS AND
9 REVOCATIONS.—

10 (1) IN GENERAL.—Each person collecting or
11 storing protected health information shall maintain
12 a record for a period of 7 years of each authoriza-
13 tion of an individual and revocation thereof.

14 (2) RULE OF CONSTRUCTION.—Records of au-
15 thorizations and revocations maintained under para-
16 graph (1) shall not be construed to be protected
17 health information under this Act.

18 (e) NO WAIVER.— Except as provided for in this Act,
19 an authorization to disclose protected health information
20 by an individual shall not be construed as a waiver of any
21 rights that the individual has under other Federal or State
22 laws, the rules of evidence, or common law.

23 (f) RULE OF CONSTRUCTION.—Authorizations for
24 the disclosure of protected health information for treat-
25 ment, payment, and health care operations shall not au-

1 authorize the disclosure of such information by an individual
2 with the intent to sell, transfer, or use protected health
3 information for the purpose of marketing a product or
4 service. For such disclosures a separate authorization is
5 required under section 203.

6 **SEC. 203. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**
7 **TECTED HEALTH INFORMATION OTHER THAN**
8 **FOR TREATMENT, PAYMENT, OR HEALTH**
9 **CARE OPERATIONS.**

10 (a) WRITTEN AUTHORIZATIONS.—A health care pro-
11 vider, health plan, health oversight agency, health re-
12 searcher, public health authority, law enforcement official,
13 employer, health or life insurer, school, or university may
14 disclose protected health information, for purposes other
15 than those authorized under section 202, pursuant to an
16 authorization executed by the individual who is the subject
17 of the information that meets the requirements of section
18 202(b). Such an authorization shall be separate from an
19 authorization provided under section 202.

20 (b) LIMITATION ON AUTHORIZATIONS.—An entity
21 described in section 202 may not condition the delivery
22 of treatment or payment for services on the receipt of an
23 authorization described in this section.

24 (c) REVOCATION OR AMENDMENT OF AUTHORIZA-
25 TION.—

1 (1) IN GENERAL.—An individual may in writing
2 revoke or amend an authorization described in sub-
3 section (a).

4 (2) NOTICE OF REVOCATION.—An entity de-
5 scribed in subsection (a) that discloses protected
6 health information pursuant to an authorization that
7 has been revoked under paragraph (1) shall not be
8 subject to any liability or penalty under this title if
9 that entity had no actual or constructive notice of
10 the revocation.

11 (d) REQUIREMENT TO RELEASE PROTECTED
12 HEALTH INFORMATION TO CORONERS AND MEDICAL EX-
13 AMINERS.—

14 (1) IN GENERAL.—When a Coroner or Medical
15 Examiner or their duly appointed deputies seek pro-
16 tected health information for the purpose of inquiry
17 into and determination of, the cause, manner, and
18 circumstances of a death, the health care provider,
19 health plan, health oversight agency, public health
20 authority, employer, health or life insurer, health re-
21 searcher, law enforcement official, school, or univer-
22 sity involved shall provide the protected health infor-
23 mation to the Coroner or Medical Examiner or to
24 the duly appointed deputies without undue delay.

1 (2) PRODUCTION OF ADDITIONAL INFORMA-
2 TION.—If a Coroner or Medical Examiner or their
3 duly appointed deputies receives health information
4 from an entity referred to in paragraph (1), such
5 health information shall remain as protected health
6 information unless the health information is at-
7 tached to or otherwise made a part of a Coroner's
8 or Medical Examiner's official report, in which case
9 it shall no longer be protected.

10 (3) EXEMPTION.—Health information attached
11 to or otherwise made a part of a Coroner's or Medi-
12 cal Examiner's official report, shall be exempt from
13 the provisions of this Act except as provided for in
14 this subsection.

15 (4) REIMBURSEMENT.—A Coroner or Medical
16 Examiner may require a person to reimburse their
17 Office for the reasonable costs associated with such
18 inspection or copying.

19 (e) DISCLOSURE FOR PURPOSE ONLY.—A recipient
20 of information pursuant to an authorization under this
21 section may use or disclose such information solely to
22 carry out the purpose for which the information was au-
23 thorized for release.

24 (f) MODEL AUTHORIZATIONS.—The Secretary, after
25 notice and opportunity for public comment, shall develop

1 and disseminate model written authorizations of the type
2 described in subsection (a). Any authorization obtained on
3 a model authorization form developed by the Secretary
4 shall be deemed to meet the authorization requirements
5 of this section.

6 **SEC. 204. NEXT OF KIN AND DIRECTORY INFORMATION.**

7 (a) NEXT OF KIN.—A health care provider, or a per-
8 son who receives protected health information under sec-
9 tion 205, may disclose protected health information re-
10 garding an individual to the individual's next of kin, an
11 individual's representative, or to another person whom the
12 individual has identified, if—

13 (1) the individual who is the subject of the
14 information—

15 (A) has been notified of the individual's
16 right to object to such disclosure and the indi-
17 vidual has not objected to the disclosure; or

18 (B) is in a physical or mental condition
19 such that the individual is not capable of object-
20 ing, and there are no prior indications that the
21 individual would object;

22 (2) the information disclosed relates to health
23 care currently being provided to that individual; or

(3) the disclosure of the protected health information is consistent with good medical or professional practice.

(b) DIRECTORY INFORMATION.—

(1) DISCLOSURE.—

(A) IN GENERAL.—Except as provided in paragraph (2), an entity described in subsection (a) may disclose the information described in subparagraph (B) to any person if the individual who is the subject of the information—

(i) has been notified of the individual's right to object and the individual has not objected to the disclosure; or

(ii) is in a physical or mental condition such that the individual is not capable of objecting, the individual's next of kin has not objected, and there are no prior indications that the individual would object.

(B) INFORMATION.—Information described in this subparagraph is information that consists only of 1 or more of the following items:

(i) The name of the individual who is the subject of the information.

(ii) The general health status of the individual, described as critical, poor, fair,

1 stable, or satisfactory or in terms denoting
2 similar conditions.

3 (iii) The location of the individual on
4 premises controlled by a provider.

5 (2) EXCEPTION.—

6 (A) LOCATION.—Paragraph (1)(B)(iii)
7 shall not apply if disclosure of the location of
8 the individual would reveal specific information
9 about the physical or mental condition of the
10 individual, unless the individual expressly au-
11 thorizes such disclosure.

12 (B) DIRECTORY OR NEXT OF KIN INFOR-
13 MATION.—A disclosure may not be made under
14 this section if the health care provider involved
15 has reason to believe that the disclosure of di-
16 rectory or next of kin information could lead to
17 the physical or mental harm of the individual,
18 unless the individual expressly authorizes such
19 disclosure.

20 (c) IDENTIFICATION OF DECEASED INDIVIDUAL.—

21 An entity described in subsection (a) may disclose pro-
22 tected health information if such disclosure is necessary
23 to assist in the identification or safe handling of a de-
24 ceased individual.

25 (d) RIGHTS OF MINORS.—

1 (1) INDIVIDUALS WHO ARE 18 OR LEGALLY CA-
2 PABLE.—In the case of an individual—

3 (A) who is 18 years of age or older, all
4 rights of the individual under this title shall be
5 exercised by the individual; or

6 (B) who, acting alone, can obtain a type of
7 health care without violating any applicable
8 Federal or State law, and who has sought such
9 care, the individual shall exercise all rights of
10 the individual under this title with respect to
11 protected health information relating to such
12 health care.

13 (2) INDIVIDUALS UNDER 18.—Except as pro-
14 vided in paragraph (1)(B), in the case of an individ-
15 ual who is—

16 (A) under 14 years of age, all of the indi-
17 vidual's rights under this title shall be exercised
18 through the parent or legal guardian; or

19 (B) at least 14 but under 18 years of age,
20 the rights of inspection and amendment, and
21 the right to authorize use and disclosure of pro-
22 tected health information of the individual shall
23 be exercised by the individual, or by the parent
24 or legal guardian of the individual.

1 **SEC. 205. EMERGENCY CIRCUMSTANCES.**

2 Any person who creates or receives protected health
3 information under this title may disclose protected health
4 information in emergency circumstances when necessary
5 to protect the health or safety of the individual who is
6 the subject of such information from serious, imminent
7 harm. No disclosure made in the good faith belief that
8 the disclosure was necessary to protect the health or safety
9 or an individual from serious, imminent harm shall be in
10 violation of, or punishable under, this Act.

11 **SEC. 206. OVERSIGHT.**

12 (a) IN GENERAL.—A health care provider, health
13 plan, employer, health or life insurer, law enforcement of-
14 ficial, school, or university may disclose protected health
15 information to a health oversight agency for purposes of
16 an oversight function authorized by law.

17 (b) PUBLIC HEALTH AND HEALTH RESEARCH.—A
18 public health authority or health researcher may disclose
19 protected health information to a health oversight agency
20 for purposes of an oversight function of the public health
21 authority or health researcher authorized by law.

22 (c) AUTHORIZATION BY A SUPERVISOR.—For pur-
23 poses of this section, the individual with authority to au-
24 thorize the oversight function involved shall provide to the
25 entity described in subsection (a) or (b) a statement that

1 the protected health information is being sought for a le-
2 gally authorized oversight function.

3 (d) USE IN ACTION AGAINST INDIVIDUALS.—Pro-
4 tected health information about an individual that is dis-
5 closed under this section may not be used in, or disclosed
6 to any person for use in, an administrative, civil, or crimi-
7 nal action or investigation directed against the individual
8 unless the action or investigation arises out of and is di-
9 rectly related to—

10 (1) the receipt of health care or payment for
11 health care;

12 (2) an action involving a fraudulent claim relat-
13 ed to health; or

14 (3) an action involving oversight of a public
15 health authority or a health researcher.

16 **SEC. 207. PUBLIC HEALTH.**

17 A health care provider, health plan, public health au-
18 thority, employer, health or life insurer, law enforcement
19 official, school, or university may disclose protected health
20 information to a public health authority or other person
21 authorized by law for use in a legally authorized—

22 (1) disease or injury report;

23 (2) public health surveillance; or

24 (3) public health investigation or intervention.

1 **SEC. 208. HEALTH RESEARCH.**

2 (a) IN GENERAL.—A health care provider, health
3 plan, public health authority, employer, health or life in-
4 surer, school, or university may disclose protected health
5 information to a health researcher if—

6 (1) the research involves human subjects con-
7 ducted or supported by any Federal department or
8 agency and the researcher complies with the com-
9 mon rule;

10 (2) the research is a clinical investigation in-
11 volving human subjects and the researcher follows
12 the regulations of the Food and Drug Administra-
13 tion governing confidentiality procedures; or

14 (3) the research is not subject to the Federal
15 Policy for the Protection of Human Subjects.

16 (b) PERIODIC REVIEW AND TECHNICAL ASSISTANCE
17 OF INSTITUTIONAL REVIEW BOARDS INVOLVED WITH
18 THE FEDERAL POLICY FOR PROTECTION OF HUMAN
19 SUBJECTS.—

20 (1) INSTITUTIONAL REVIEW BOARD.—Any in-
21 stitutional review board that authorizes research
22 under this section pursuant to the common rule shall
23 keep records of the names and addresses of all mem-
24 bers who participate in such authorizations for pos-
25 sible review or audit.

1 (2) TECHNICAL ASSISTANCE.—The Secretary
2 may provide technical assistance to institutional re-
3 view boards described in this section.

4 (3) MONITORING.—The Secretary shall periodi-
5 cally monitor institutional review boards described in
6 this section.

7 (4) REPORTS.—Not later than 3 years after the
8 date of enactment of this Act, the Secretary shall re-
9 port to Congress regarding the activities of institu-
10 tional review boards described in this section.

11 (c) REVIEW OF THE COMMON RULE BY THE SEC-
12 RETARY.—The Secretary shall review the requirements of
13 the common rule pertaining to the privacy of protected
14 health information and shall promulgate any amendments
15 to the common rule that may be necessary to ensure the
16 confidentiality of such information.

17 (d) RECOMMENDATIONS WITH RESPECT TO PRI-
18 VACY.—

19 (1) IN GENERAL.—Not later than the date that
20 is 12 months after the date of the enactment of this
21 Act, the Secretary shall submit to the Committee on
22 Labor and Human Resources of the Senate detailed
23 recommendations on standards with respect to the
24 privacy of individually identifiable health information
25 in research described in subsection (a)(3).

1 (2) RULE OF CONSTRUCTION.—In formulating
 2 the recommendations under paragraph (1), the Sec-
 3 retary shall consider the findings of the National
 4 Bioethics Advisory Commission and the results of
 5 the General Accounting Office report authorized by
 6 section 402.

7 (3) REGULATIONS.—If legislation governing
 8 standards with respect to the privacy of individually
 9 identifiable health information transmitted in con-
 10 nection with research described in subsection (a)(3)
 11 is not enacted by the date that is 24 months after
 12 the date of the enactment of this Act, the Secretary
 13 shall promulgate final regulations containing such
 14 standards not later than the date that is 30 months
 15 after the date of the enactment of this Act.

16 **SEC. 209. DISCLOSURE IN CIVIL, JUDICIAL, AND ADMINIS-**
 17 **TRATIVE PROCEDURES.**

18 (a) IN GENERAL.—A health care provider, health
 19 plan, public health authority, employer, health or life in-
 20 surer, law enforcement official, school, or university may
 21 disclose protected health information pursuant to a discov-
 22 ery request or subpoena in a civil action brought in a Fed-
 23 eral or State court or a request or subpoena related to
 24 a Federal or State administrative proceeding, but only if

1 the disclosure is made pursuant to a court order as pro-
2 vided for in subsection (b).

3 (b) COURT ORDERS.—

4 (1) STANDARD FOR ISSUANCE.—In considering
5 a request for a court order regarding the disclosure
6 of protected health information under subsection (a),
7 the court shall issue such order if the court deter-
8 mines that without the disclosure of such informa-
9 tion, the person requesting the order would be im-
10 paired from establishing a claim or defense.

11 (2) REQUIREMENTS.—An order issued under
12 paragraph (1) shall—

13 (A) provide that the protected health infor-
14 mation involved is subject to court protection;

15 (B) specify to whom the information may
16 be disclosed;

17 (C) specify that such information may not
18 otherwise be disclosed or used; and

19 (D) meet any other requirements that the
20 court determines are needed to protect the con-
21 fidentiality of the information.

22 (c) APPLICABILITY.—This section shall not apply in
23 a case in which the protected health information sought
24 under such discovery request or subpoena—

25 (1) is nonidentifiable health information;

1 (2) is related to a party to the litigation whose
2 medical condition is at issue; or

3 (3) could be disclosed under any of sections 202
4 through 208, 210, and 212.

5 (d) EFFECT OF SECTION.—This section shall not be
6 construed to supersede any grounds that may apply under
7 Federal or State law for objecting to turning over the pro-
8 tected health information.

9 **SEC. 210. DISCLOSURE FOR LAW ENFORCEMENT PUR-**
10 **POSES.**

11 (a) IN GENERAL.—A health care provider, health
12 plan, health oversight agency, employer, health or life in-
13 surer, school, university, or person who receives protected
14 health information pursuant to sections 203 through 208,
15 may disclose protected health information under this sec-
16 tion, except to a health oversight agency governed by sec-
17 tion 206, if the disclosure is pursuant to—

18 (1) a subpoena issued under the authority of a
19 grand jury;

20 (2) an administrative subpoena or summons or
21 judicial subpoena or warrant; or

22 (3) a Federal or State law requiring the report-
23 ing of specific medical information to law enforce-
24 ment authorities.

1 (b) PROBABLE CAUSE.—A subpoena or summons for
2 a disclosure under paragraph (1) or (2) of subsection (a)
3 shall only be issued if the law enforcement agency involved
4 shows that there is probable cause to believe that the in-
5 formation is relevant to a legitimate law enforcement in-
6 quiry.

7 (c) DESTRUCTION OR RETURN OF INFORMATION.—
8 When the matter or need for which protected health infor-
9 mation was disclosed to a law enforcement agency or
10 grand jury under subsection (a) has concluded, including
11 any derivative matters arising from such matter or need,
12 the law enforcement agency or grand jury shall either de-
13 stroy the protected health information, or return it to the
14 person from whom it was obtained.

15 (d) REDACTIONS.—To the extent practicable, and
16 consistent with the requirements of due process, a law en-
17 forcement agency shall redact personally identifying infor-
18 mation from protected health information prior to the
19 public disclosure of such protected information in a judi-
20 cial or administrative proceeding.

21 (e) USE OF INFORMATION.—Protected health infor-
22 mation obtained by a law enforcement agency pursuant
23 to this section may only be used for purposes of a legiti-
24 mate law enforcement activity.

1 (f) EXCLUSION OF EVIDENCE.—If protected health
2 information is obtained without meeting the requirements
3 of paragraphs (1), (2), and (3) of subsection (a), any such
4 information that is unlawfully obtained shall be excluded
5 from court proceedings unless the defendant requests oth-
6 erwise.

7 **SEC. 211. DISCLOSURES FOR POSTMARKETING ADVERSE**
8 **EXPERIENCE REPORTING FOR HUMAN DRUG**
9 **AND LICENSED BIOLOGICAL PRODUCTS.**

10 (a) ADVERSE EXPERIENCE REPORTS.—

11 (1) IN GENERAL.—Pursuant to the regulations
12 of the Food and Drug Administration at sections
13 310.305, 314.80, and 600.80 of title 21, Code of
14 Federal Regulations, manufacturers, packers, and
15 distributors of approved new drug applications, ab-
16 breviated new drug applications, antibiotic applica-
17 tions, marketed prescription of drugs for human use,
18 and approved biologic product license applications
19 shall report adverse experiences in accordance with
20 such section.

21 (2) NO IDENTIFICATION OF PATIENTS.—In ac-
22 cordance with the August 1997 Guidance for Indus-
23 try of the Food and Drug Administration, patients
24 shall not be identified by name, address, or social se-
25 curity number in any report described in paragraph

1 (1). The manufacturer, packer, or distributor in-
2 volved shall assign a code for a patient in each such
3 report.

4 (3) NON LIABILITY UNDER ACT.—A manufac-
5 turer, packer, or distributor who submits an adverse
6 report in accordance with this subsection and the
7 regulations described in paragraph (1) shall not be
8 liable under this Act.

9 (b) RULE OF CONSTRUCTION.—An adverse experi-
10 ence report written in accordance with the regulations de-
11 scribed in subsection (a) shall be deemed to be a disclosure
12 of non-identifiable information under this Act.

13 **SEC. 212. PAYMENT CARD AND ELECTRONIC PAYMENT**
14 **TRANSACTION.**

15 (a) PAYMENT FOR HEALTH CARE THROUGH CARD
16 OR ELECTRONIC MEANS.—If an individual pays for health
17 care by presenting a debit, credit, or other payment card
18 or account number, or by any other electronic payment
19 means, the entity receiving payment may disclose to a per-
20 son described in subsection (b) only such protected health
21 information about the individual as is necessary for the
22 processing of the payment transaction or the billing or col-
23 lection of amounts charged to, debited from, or otherwise
24 paid by, the individual using the card, number, or other
25 electronic means.

1 (b) TRANSACTION PROCESSING.—A person who is a
2 debit, credit, or other payment card issuer, or is otherwise
3 directly involved in the processing of payment transactions
4 involving such cards or other electronic payment trans-
5 actions, or is otherwise directly involved in the billing or
6 collection of amounts paid through such means, may use
7 or disclose protected health information about an individ-
8 ual that has been disclosed in accordance with subsection
9 (a) only when necessary for—

10 (1) the authorization, settlement, billing or col-
11 lection of amounts charged to, debited from, or oth-
12 erwise paid the individual using a debit, credit, or
13 other payment card or account number, or by other
14 electronic payment means;

15 (2) the transfer of receivables, accounts, or in-
16 terest therein;

17 (3) the audit of the debit, credit, or other pay-
18 ment card account information;

19 (4) compliance with Federal, State, or local law,
20 or

21 (5) compliance with a properly authorized civil,
22 criminal, or regulatory investigation by Federal,
23 State, or local authorities as governed by the re-
24 quirements of this section.

1 **SEC. 213. STANDARDS FOR ELECTRONIC DISCLOSURES.**

2 The Secretary shall promulgate standards for disclos-
3 ing, authorizing, and authenticating, protected health in-
4 formation in electronic form consistent with this title.

5 **SEC. 214. INDIVIDUAL REPRESENTATIVES.**

6 (a) **IN GENERAL.**—Except as provided in subsections
7 (b) and (c), a person who is authorized by law (based on
8 grounds other than the individual being a minor), or by
9 an instrument recognized under law, to act as an agent,
10 attorney, proxy, or other legal representative of a pro-
11 tected individual, may, to the extent so authorized, exer-
12 cise and discharge the rights of the individual under this
13 Act.

14 (b) **HEALTH CARE POWER OF ATTORNEY.**—A person
15 who is authorized by law (based on grounds other than
16 being a minor), or by an instrument recognized under law,
17 to make decisions about the provision of health care to
18 an individual who is incapacitated, may exercise and dis-
19 charge the rights of the individual under this Act to the
20 extent necessary to effectuate the terms or purposes of
21 the grant of authority.

22 (c) **NO COURT DECLARATION.**—If a health care pro-
23 vider determines that an individual, who has not been de-
24 clared to be legally incompetent, suffers from a medical
25 condition that prevents the individual from acting know-
26 ingly or effectively on the individual's own behalf, the right

1 of the individual to authorize disclosure under this Act
2 may be exercised and discharged in the best interest of
3 the individual by—

4 (1) a person described in subsection (b) with re-
5 spect to the individual;

6 (2) a person described in subsection (a) with re-
7 spect to the individual, but only if a person de-
8 scribed in paragraph (1) cannot be contacted after
9 a reasonable effort;

10 (3) the next of kin of the individual, but only
11 if a person described in paragraph (1) or (2) cannot
12 be contacted after a reasonable effort; or

13 (4) the health care provider, but only if a per-
14 son described in paragraph (1), (2), or (3) cannot be
15 contacted after a reasonable effort.

16 (d) APPLICATION TO DECEASED INDIVIDUALS.—The
17 provisions of this Act shall continue to apply to protected
18 health information concerning a deceased individual for a
19 period of 2-years following the death of that individual.

20 (e) EXERCISE OF RIGHTS ON BEHALF OF A DE-
21 CEASED INDIVIDUAL.—A person who is authorized by law
22 or by an instrument recognized under law, to act as an
23 executor of the estate of a deceased individual, or other-
24 wise to exercise the rights of the deceased individual, may,
25 to the extent so authorized, exercise and discharge the

1 rights of such deceased individual under this Act for a pe-
2 riod of 2-years following the death of that individual. If
3 no such designee has been authorized, the rights of the
4 deceased individual may be exercised as provided for in
5 subsection (c).

6 **SEC. 215. LIMITED LIABILITY FOR LAW ENFORCEMENT OF-**
7 **FICERS.**

8 Federal and State law enforcement officers shall not
9 be personally liable for violations of this Act unless it is
10 shown that the violation was a result of intentional con-
11 duct committed with the intent to sell, transfer, or use
12 protected health information for commercial advantage,
13 personal gain, or malicious harm.

14 **SEC. 216. NO LIABILITY FOR PERMISSIBLE DISCLOSURES.**

15 A health care provider, health plan, health oversight
16 agency, health researcher, public health authority, law en-
17 forcement official, employer, health or life insurer, school,
18 or university who makes a disclosure of protected health
19 information about an individual that is permitted by this
20 Act shall not be liable to the individual for such disclosure
21 under common law.

TITLE III—SANCTIONS

Subtitle A—Criminal Provisions

SEC. 301. WRONGFUL DISCLOSURE OF PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—Part I of title 18, United States Code, is amended by adding at the end the following:

“CHAPTER 124—WRONGFUL DISCLOSURE OF PROTECTED HEALTH INFORMATION

“Sec.

“2801. Wrongful disclosure of protected health information.

“§ 2801. Wrongful disclosure of protected health in- formation

“(a) OFFENSE.—The penalties described in subsection (b) shall apply to a person that knowingly and intentionally—

“(1) obtains protected health information relating to an individual in violation of title II of the Health Care PIN Act;

“(2) discloses protected health information to another person in violation of title II of the Health Care PIN Act; or

“(3) uses protected health information in violation of title II of the Health Care PIN Act.

“(b) PENALTIES.—A person described in subsection (a) shall—

1 “(1) be fined not more than \$50,000, impris-
2 oned not more than 1 year, or both;

3 “(2) if the offense is committed under false pre-
4 tenses, be fined not more than \$250,000, imprisoned
5 not more than 5 years, or any combination of such
6 penalties;

7 “(3) if the offense is committed with the intent
8 to sell, transfer, or use protected health information
9 for commercial advantage, personal gain, or mali-
10 cious harm, be fined not more than \$500,000, im-
11 prisoned not more than 10 years, excluded from par-
12 ticipation in any federally funded health care pro-
13 grams, or any combination of such penalties.

14 “(c) SUBSEQUENT OFFENSES.—In the case of a per-
15 son described in subsection (a), the maximum penalties
16 described in subsection (b) shall be doubled for every sub-
17 sequent conviction for an offense arising out of a violation
18 or violations related to a set of circumstances that are dif-
19 ferent from those involved in the previous violation or set
20 of related violations described in such subsection (a).”.

21 (b) CLERICAL AMENDMENT.—The table of chapters
22 for part I of title 18, United States Code, is amended by
23 inserting after the item relating to chapter 123 the follow-
24 ing new item:

“124. Wrongful disclosure of protected health information 2801”.

1 **SEC. 302. DEBARMENT FOR CRIMES.**

2 (a) PURPOSE.—The purpose of this section is to pro-
3 mote the prevention and deterrence of instances of inten-
4 tional criminal actions which violate criminal laws which
5 are designed to safeguard the protected health information
6 in a manner consistent with this Act.

7 (b) DEBARMENT.—Not later than 270 days after the
8 effective date of this Act, the Attorney General, in con-
9 sultation with the Secretary, shall promulgate regulations
10 and establish procedures to permit the debarment of
11 health care providers, health researchers, health or life in-
12 surers, or schools or universities from receiving benefits
13 under any Federal health programs if the managers or
14 officers of such entities are found guilty of violating sec-
15 tion 2801 of title 18, United States Code, have civil pen-
16 alties imposed against such officers or managers under
17 section 311 in connection with the illegal disclosure of pro-
18 tected health information, or are found guilty of making
19 a false statement or obstructing justice related to attempt-
20 ing to conceal or concealing such illegal disclosure. Such
21 regulations shall take into account the need for continuity
22 of medical care and may provide for a delay of any debar-
23 ment imposed under this section to take into account the
24 medical needs of patients.

25 (c) CONSULTATION.—Before publishing a proposed
26 rule to implement subsection (b), the Attorney General

1 shall consult with State law enforcement officials, health
2 care providers, patient privacy rights' advocates, and other
3 appropriate individuals and entities, to gain additional in-
4 formation regarding the debarment of entities under sub-
5 section (b) and the best methods to ensure the continuity
6 of medical care.

7 (d) REPORT.—The Attorney General shall annually
8 prepare and submit to the Committee on the Judiciary of
9 the House of Representatives and the Committee on the
10 Judiciary of the Senate a report concerning the activities
11 and debarment actions taken by the Attorney General
12 under this section.

13 (e) ASSISTANCE TO PREVENT CRIMINAL VIOLA-
14 TIONS.—The Attorney General, in cooperation with any
15 other appropriate individual, organization, or agency, may
16 provide advice, training, technical assistance, and guid-
17 ance regarding ways to reduce the incidence of improper
18 disclosure of protected health information.

19 (f) RELATIONSHIP TO OTHER AUTHORITIES.—A de-
20 barment imposed under this section shall not reduce or
21 diminish the authority of a Federal, State, or local govern-
22 mental agency or court to penalize, imprison, fine, sus-
23 pend, debar, or take other adverse action against a person,
24 in a civil, criminal, or administrative proceeding.

1 **Subtitle B—Civil Sanctions**

2 **SEC. 311. CIVIL PENALTY.**

3 (a) VIOLATION.—A health care provider, health re-
4 searcher, health plan, health oversight agency, public
5 health agency, law enforcement agency, employer, health
6 or life insurer, school, or university, or the agent of any
7 such individual or entity, who the Secretary, in consulta-
8 tion with the Attorney General, determines has substan-
9 tially and materially failed to comply with this Act shall
10 be subject, in addition to any other penalties that may
11 be prescribed by law—

12 (1) in a case in which the violation relates to
13 title I, to a civil penalty of not more than \$500 for
14 each such violation, but not to exceed \$5,000 in the
15 aggregate for multiple violations;

16 (2) in a case in which the violation relates to
17 title II, to a civil penalty of not more than \$10,000
18 for each such violation, but not to exceed \$50,000
19 in the aggregate for multiple violations; or

20 (3) in a case in which the Secretary finds that
21 such violations have occurred with such frequency as
22 to constitute a general business practice, to a civil
23 penalty of not more than \$100,000.

24 (b) PROCEDURES FOR IMPOSITION OF PENALTIES.—
25 Section 1128A of the Social Security Act, other than sub-

1 sections (a) and (b) and the second sentence of subsection
2 (f) of that section, shall apply to the imposition of a civil,
3 monetary, or exclusionary penalty under this section in the
4 same manner as such provisions apply with respect to the
5 imposition of a penalty under section 1128A of such Act.

6 **SEC. 312. PROCEDURES FOR IMPOSITION OF PENALTIES.**

7 (a) INITIATION OF PROCEEDINGS.—

8 (1) IN GENERAL.—The Secretary, in consulta-
9 tion with the Attorney General, may initiate a pro-
10 ceeding to determine whether to impose a civil
11 money penalty under section 311. The Secretary
12 may not initiate an action under this section with re-
13 spect to any violation described in section 311 after
14 the expiration of the 6-year period beginning on the
15 date on which such violation was alleged to have oc-
16 curred. The Secretary may initiate an action under
17 this section by serving notice of the action in any
18 manner authorized by Rule 4 of the Federal Rules
19 of Civil Procedure.

20 (2) NOTICE AND OPPORTUNITY FOR HEAR-
21 ING.—The Secretary shall not make a determination
22 adverse to any person under paragraph (1) until the
23 person has been given written notice and an oppor-
24 tunity for the determination to be made on the
25 record after a hearing at which the person is entitled

1 to be represented by counsel, to present witnesses,
2 and to cross-examine witnesses against the person.

3 (3) ESTOPPEL.—In a proceeding under para-
4 graph (1) that—

5 (A) is against a person who has been con-
6 victed (whether upon a verdict after trial or
7 upon a plea of guilty or nolo contendere) of a
8 crime under section 2801 of title 18, United
9 States Code; and

10 (B) involves the same conduct as in the
11 criminal action;

12 the person is estopped from denying the essential
13 elements of the criminal offense.

14 (4) SANCTIONS FOR FAILURE TO COMPLY.—

15 The official conducting a hearing under this section
16 may sanction a person, including any party or attor-
17 ney, for failing to comply with an order or proce-
18 dure, failing to defend an action, or other mis-
19 conduct as would interfere with the speedy, orderly,
20 or fair conduct of the hearing. Such sanction shall
21 reasonably relate to the severity and nature of the
22 failure or misconduct. Such sanction may include—

23 (A) in the case of refusal to provide or per-
24 mit discovery, drawing negative factual infer-
25 ences or treating such refusal as an admission

1 by deeming the matter, or certain facts, to be
2 established;

3 (B) prohibiting a party from introducing
4 certain evidence or otherwise supporting a par-
5 ticular claim or defense;

6 (C) striking pleadings, in whole or in part;

7 (D) staying the proceedings;

8 (E) dismissal of the action;

9 (F) entering a default judgment;

10 (G) ordering the party or attorney to pay
11 attorneys' fees and other costs caused by the
12 failure or misconduct; and

13 (H) refusing to consider any motion or
14 other action which is not filed in a timely man-
15 ner.

16 (b) SCOPE OF PENALTY.—In determining the
17 amount or scope of any penalty imposed pursuant to sec-
18 tion 311, the Secretary shall take into account—

19 (1) the nature of claims and the circumstances
20 under which they were presented;

21 (2) the degree of culpability, history of prior of-
22 fenses, and financial condition of the person present-
23 ing the claims; and

24 (3) such other matters as justice may require.

25 (c) REVIEW OF DETERMINATION.—

1 (1) IN GENERAL.—Any person adversely af-
2 fected by a determination of the Secretary under
3 this section may obtain a review of such determina-
4 tion in the United States Court of Appeals for the
5 circuit in which the person resides, or in which the
6 claim was presented, by filing in such court (within
7 60 days following the date the person is notified of
8 the determination of the Secretary) a written peti-
9 tion requesting that the determination be modified
10 or set aside.

11 (2) FILING OF RECORD.—A copy of the petition
12 filed under paragraph (1) shall be forthwith trans-
13 mitted by the clerk of the court to the Secretary,
14 and thereupon the Secretary shall file in the Court
15 the record in the proceeding as provided in section
16 2112 of title 28, United States Code. Upon such fil-
17 ing, the court shall have jurisdiction of the proceed-
18 ing and of the question determined therein, and
19 shall have the power to make and enter upon the
20 pleadings, testimony, and proceedings set forth in
21 such record a decree affirming, modifying, remand-
22 ing for further consideration, or setting aside, in
23 whole or in part, the determination of the Secretary
24 and enforcing the same to the extent that such order
25 is affirmed or modified.

1 (3) CONSIDERATION OF OBJECTIONS.—No ob-
2 jection that has not been raised before the Secretary
3 with respect to a determination described in para-
4 graph (1) shall be considered by the court, unless
5 the failure or neglect to raise such objection shall be
6 excused because of extraordinary circumstances.

7 (4) FINDINGS.—The findings of the Secretary
8 with respect to questions of fact in an action under
9 this subsection, if supported by substantial evidence
10 on the record considered as a whole, shall be conclu-
11 sive. If any party shall apply to the court for leave
12 to adduce additional evidence and shall show to the
13 satisfaction of the court that such additional evi-
14 dence is material and that there were reasonable
15 grounds for the failure to adduce such evidence in
16 the hearing before the Secretary, the court may
17 order such additional evidence to be taken before the
18 Secretary and to be made a part of the record. The
19 Secretary may modify findings as to the facts, or
20 make new findings, by reason of additional evidence
21 so taken and filed, and shall file with the court such
22 modified or new findings, and such findings with re-
23 spect to questions of fact, if supported by substan-
24 tial evidence on the record considered as a whole,
25 and the recommendations of the Secretary, if any,

1 for the modification or setting aside of the original
2 order, shall be conclusive.

3 (5) EXCLUSIVE JURISDICTION.—Upon the filing
4 of the record with the court under paragraph (2),
5 the jurisdiction of the court shall be exclusive and its
6 judgment and decree shall be final, except that the
7 same shall be subject to review by the Supreme
8 Court of the United States, as provided for in sec-
9 tion 1254 of title 28, United States Code.

10 (d) RECOVERY OF PENALTIES.—

11 (1) IN GENERAL.—Civil money penalties im-
12 posed under this subtitle may be compromised by
13 the Secretary and may be recovered in a civil action
14 in the name of the United States brought in United
15 States district court for the district where the claim
16 was presented, or where the claimant resides, as de-
17 termined by the Secretary. Amounts recovered under
18 this section shall be paid to the Secretary and depos-
19 ited as miscellaneous receipts of the Treasury of the
20 United States.

21 (2) DEDUCTION FROM AMOUNTS OWING.—The
22 amount of any penalty, when finally determined
23 under this section, or the amount agreed upon in
24 compromise under paragraph (1), may be deducted
25 from any sum then or later owing by the United

1 States or a State to the person against whom the
2 penalty has been assessed.

3 (e) DETERMINATION FINAL.—A determination by
4 the Secretary to impose a penalty under section 321 shall
5 be final upon the expiration of the 60-day period referred
6 to in subsection (c)(1). Matters that were raised or that
7 could have been raised in a hearing before the Secretary
8 or in an appeal pursuant to subsection (c) may not be
9 raised as a defense to a civil action by the United States
10 to collect a penalty under section 311.

11 (f) SUBPOENA AUTHORITY.—

12 (1) IN GENERAL.—For the purpose of any
13 hearing, investigation, or other proceeding author-
14 ized or directed under this section, or relative to any
15 other matter within the jurisdiction of the Attorney
16 General hereunder, the Attorney General, acting
17 through the Secretary shall have the power to issue
18 subpoenas requiring the attendance and testimony of
19 witnesses and the production of any evidence that
20 relates to any matter under investigation or in ques-
21 tion before the Secretary. Such attendance of wit-
22 nesses and production of evidence at the designated
23 place of such hearing, investigation, or other pro-
24 ceeding may be required from any place in the

1 United States or in any Territory or possession
2 thereof.

3 (2) SERVICE.—Subpoenas of the Secretary
4 under paragraph (1) shall be served by anyone au-
5 thorized by the Secretary by delivering a copy there-
6 of to the individual named therein.

7 (3) PROOF OF SERVICE.—A verified return by
8 the individual serving the subpoena under this sub-
9 section setting forth the manner of service shall be
10 proof of service.

11 (4) FEES.—Witnesses subpoenaed under this
12 subsection shall be paid the same fees and mileage
13 as are paid witnesses in the district court of the
14 United States.

15 (5) REFUSAL TO OBEY.—In case of contumacy
16 by, or refusal to obey a duly served upon, any per-
17 son, any district court of the United States for the
18 judicial district in which such person charged with
19 contumacy or refusal to obey is found or resides or
20 transacts business, upon application by the Sec-
21 retary, shall have jurisdiction to issue an order re-
22 quiring such person to appear and give testimony, or
23 to appear and produce evidence, or both. Any failure
24 to obey such order of the court may be punished by
25 the court as contempt thereof.

1 (g) INJUNCTIVE RELIEF.—Whenever the Secretary
2 has reason to believe that any person has engaged, is en-
3 gaging, or is about to engage in any activity which makes
4 the person subject to a civil monetary penalty under sec-
5 tion 311, the Secretary may bring an action in an appro-
6 priate district court of the United States (or, if applicable,
7 a United States court of any territory) to enjoin such ac-
8 tivity, or to enjoin the person from concealing, removing,
9 encumbering, or disposing of assets which may be required
10 in order to pay a civil monetary penalty if any such pen-
11 alty were to be imposed or to seek other appropriate relief.

12 (h) AGENCY.—A principal is liable for penalties
13 under section 311 for the actions of the principal's agent
14 acting within the scope of the agency.

15 **SEC. 313. REPORT ON USE OF EXISTING ENFORCEMENT**
16 **MECHANISMS.**

17 In addition to the criminal and civil penalties that
18 may be applied under this title, the Secretary shall prepare
19 and submit to Congress a report regarding the use of ex-
20 isting Federal, State and other licensure, certification and
21 regulatory mechanisms, including State insurance regula-
22 tions, for the imposition of sanctions or penalties for the
23 wrongful disclosure of protected health information.

1 **SEC. 314. CIVIL ACTION BY INDIVIDUALS.**

2 (a) IN GENERAL.—Any individual whose rights under
3 this Act have been knowingly or negligently violated may
4 bring a civil action to recover—

5 (1) such preliminary and equitable relief as the
6 court determines to be appropriate; and

7 (2) the greater of compensatory damages or liq-
8 uidated damages of \$5,000.

9 (b) PUNITIVE DAMAGES.—In any action brought
10 under this section in which the individual has prevailed
11 because of a knowing violation of a provision of this Act,
12 the court may, in addition to any relief awarded under
13 subsection (a), award such punitive damages as may be
14 appropriate.

15 (c) ATTORNEY'S FEES.—In the case of a civil action
16 brought under subsection (a) in which the individual has
17 substantially prevailed, the court may assess against the
18 respondent a reasonable attorney's fee and other litigation
19 costs and expenses (including expert fees) reasonably in-
20 curred.

21 (d) LIMITATION.—No action may be commenced
22 under this section more than 3 years after the date on
23 which the violation was or should reasonably have been
24 discovered.

1 **TITLE IV—MISCELLANEOUS**

2 **SEC. 401. RELATIONSHIP TO OTHER LAWS.**

3 (a) STATE AND FEDERAL LAW.—

4 (1) STATE LAW ENACTED PRIOR TO EFFECTIVE
5 DATE.—Nothing in this Act shall be construed to su-
6 persede any provision of State law that establishes,
7 implements, or continues in effect any standard or
8 requirement relating to the privacy of protected
9 health information if such provision is enacted prior
10 to the effective date of this Act. Such laws shall not
11 be superseded after such effective date to the extent
12 that such laws are at least as protective of the pri-
13 vacy of protected health information as the protec-
14 tions provided under this Act.

15 (2) STATE LAW ENACTED AFTER EFFECTIVE
16 DATE.—Except as provided in subsections (b) and
17 (c), the provisions of this Act shall preempt any
18 State law relating to the privacy of protected health
19 information if such law is enacted after the effective
20 date of this Act.

21 (3) FEDERAL LAW.—Nothing in this Act shall
22 be construed as repealing, explicitly or implicitly,
23 other Federal laws or regulations relating to pro-
24 tected health information or relating to an individ-

1 ual's access to protected health information or
2 health care services.

3 (b) PRIVILEGES.—Nothing in this title shall be con-
4 strued to preempt or modify any provisions of State statu-
5 tory or common law to the extent that such law concerns
6 a privilege of a witness or person in a court of that State.
7 This title shall not be construed to supersede or modify
8 any provision of Federal statutory or common law to the
9 extent such law concerns a privilege of a witness or person
10 in a court of the United States. Authorizations pursuant
11 to sections 202 and 203 shall not be construed as a waiver
12 of any such privilege.

13 (c) CERTAIN DUTIES UNDER LAW.—Nothing in this
14 title shall be construed to preempt, supersede, or modify
15 the operation of any State law that—

16 (1) provides for the reporting of vital statistics
17 such as birth or death information;

18 (2) requires the reporting of abuse or neglect
19 information about any individual;

20 (3) relates to public or mental health and that
21 prevents or otherwise restricts disclosure of informa-
22 tion otherwise permissible under this Act;

23 (4) governs a minor's right to access protected
24 health information or health care services; or

(5) authorizes the collecting, analysis, or dissemination of information from an entity described in section 201(a) for the purpose of developing use, cost effectiveness, performance, or quality data.

(d) FEDERAL PRIVACY ACT.—

(1) MEDICAL EXEMPTIONS.—Sections 552a of title 5, United States Code, is amended by adding at the end thereof the following: “The head of an agency that is an entity described in section 311(a) of the Health Care PIN Act shall promulgate rules, in accordance with the requirements (including general notice) of subsections (b)(1), (b)(2), (b)(3), (c), and (e) of section 553 of this title, to exempt a system of records within an agency, to the extent that the system of records contains protected health information (as defined in section 4(20) of such Act), from all provisions of this section except subsections (b)(6), (d), (e)(1), (e)(2), subparagraphs (A) and (C) and (E) through (I) of subsection (e)(4), and subsections (e)(5), (e)(6), (e)(9), (e)(12), (l), (n), (o), (p), (r), and (u).”.

(2) TECHNICAL AMENDMENT.—Section 552a(f)(3) of title 5, United States Code, is amended by striking “pertaining to him,” and all that fol-

1 lows through the semicolon and inserting “pertain-
2 ing to the individual.”

3 (e) APPLICATION TO CERTAIN FEDERAL AGEN-
4 CIES.—

5 (1) DEPARTMENT OF DEFENSE.—

6 (A) EXCEPTIONS.—The Secretary of De-
7 fense may, by regulation, establish exceptions to
8 the disclosure requirements of this Act to the
9 extent such Secretary determines that disclo-
10 sure of protected health information relating to
11 members of the armed forces from systems of
12 records operated by the Department of Defense
13 is necessary under circumstances different from
14 those permitted under this Act for the proper
15 conduct of national defense functions by mem-
16 bers of the armed forces.

17 (B) APPLICATION TO CIVILIAN EMPLOY-
18 EES.—The Secretary of Defense may, by regu-
19 lation, establish for civilian employees of the
20 Department of Defense and employees of De-
21 partment of Defense contractors, limitations on
22 the right of such persons to revoke or amend
23 authorizations for disclosures under section 203
24 when such authorizations were provided by such
25 employees as a condition of employment and

1 the disclosure is determined necessary by the
2 Secretary of Defense to the proper conduct of
3 national defense functions by such employees.

4 (2) DEPARTMENT OF TRANSPORTATION.—

5 (A) EXCEPTIONS.—The Secretary of
6 Transportation may, with respect to members
7 of the Coast Guard, exercise the same powers
8 as the Secretary of Defense may exercise under
9 paragraph (1)(A).

10 (B) APPLICATION TO CIVILIAN EMPLOY-
11 EES.—The Secretary of Transportation may,
12 with respect to civilian employees of the Coast
13 Guard and Coast Guard contractors, exercise
14 the same powers as the Secretary of Defense
15 may exercise under paragraph (1)(B).

16 (3) DEPARTMENT OF VETERANS AFFAIRS.—

17 The limitations on use and disclosure of protected
18 health information under this Act shall not be con-
19 strued to prevent any exchange of such information
20 within and among components of the Department of
21 Veterans Affairs that determine eligibility for or en-
22 titlement to, or that provide, benefits under laws ad-
23 ministered by the Secretary of Veteran Affairs.



1 **SEC. 402. EFFECTIVE DATE.**

2 (a) **EFFECTIVE DATE.**—Except as provided in sub-
3 section (b), this Act shall take effect on the date that is
4 18 months after the date of enactment of this Act.

5 (b) **REGULATIONS.**—The Secretary shall promulgate
6 regulations implementing this Act not later than 12
7 months after the date of enactment of this Act.

○